

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant):

EPA Company No. 11556

Elanco US Inc
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2. Regulatory Action for which this package is submitted:

Response to 6(a)(2) request for additional information related to PNR 1427 Insecticide (ABN Seresto; EPA Reg. No. 11556-155)

3. Transmittal Date:

May 23, 2021

4. List of Submitted Documents:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
<u>51585200</u>	ADMIN	<u>Administrative Materials</u> Submission cover letter Transmittal document Certification with respect to citation of data Document index Data matrix – confidential and sanitized versions	-----
<u>NA</u>	1 of 18	Prevalence of <i>Borrelia burgdorferi</i> , <i>Anaplasma</i> spp., <i>Ehrlichia</i> spp. and <i>Dirofilaria immitis</i> in Canadian dogs, 2008 to 2015: a repeat cross-sectional study. Evason, et al; 2019.	NA
<u>NA</u>	2 of 18	Prevention of transmission of <i>Borrelia burgdorferi</i> sensu lato and <i>Anaplasma phagocytophilum</i> by <i>Ixodes</i> spp. ticks to dogs treated with the Seresto® collar (imidacloprid 10% + flumethrin 4.5%). Krämer, et al; 2019.	NA
<u>NA</u>	3 of 18	Imidacloprid 10 % / Flumethrin 4.5 % Collars (Seresto®, Bayer) Successfully Prevent Long-Term Transmission of <i>Ehrlichia canis</i> by Infected <i>Rhipicephalus sanguineus</i> Ticks to Dogs. Stanneck and Fourie; 2013.	NA
<u>NA</u>	4 of 18	LL-AB-death-20120101 to 20201231	
<u>NA</u>	5 of 18	Banfield State of Pet Health Report 2013 Lifespan Dogs and Cats	

NA	6 of 18	US Seresto Technical Manual	NA
<u>51585201</u>	7 of 18	ID 008036; BAY Vq 1950 – Subchronic toxicity study in dogs with oral administration (13-week feeding study)	NA
<u>51585202</u>	8 of 18	ID 035962; Method for the LC-MS/MS determination of Imidacloprid and Flumethrin in cotton gloves	NA
<u>51585203</u>	9 of 18	ID 035992; Dosage of the imidacloprid 10%/flumethrin 4.5% collar and release of the active ingredients over time in cats and dogs	NA
<u>51585204</u>	10 of 18	ID 044762; Plasma pharmacokinetics of imidacloprid and flumethrin in dogs after topical treatment using a collar (Seresto®) containing 10% imidacloprid and 4.5% flumethrin with special regard to the first 7 days of use	NA
<u>51585205</u>	11 of 18	ID 045266; Plasma pharmacokinetics of imidacloprid after single oral administration to dogs	NA
<u>51585206</u>	12 of 18	ID 045267; Plasma pharmacokinetics of flumethrin after single oral administration to dogs	NA
<u>51585207</u>	13 of 18	ID 048168; Seresto – Review of PMRA Assessment	NA
<u>51585208</u>	14 of 18	ID 048173; Seresto Collar (Cats & Dogs) Case Review (Deaths: ABON Coded A & B)	NA
<u>51585209</u>	15 of 18	ID 048179; Seresto® Collar Cats and Dogs (Imidacloprid and Flumethrin) Bayer Animal Health Response Document to PMRA Meeting of July 14 2016	NA
<u>51585210</u>	16 of 18	ID 048180; Bayer Animal Health Critique of PMRA's Animal Incident Assessment for the Seresto® Collar 02 Sep 2016	NA
<u>51585211</u>	17 of 18	ID 048181; Bayer Animal Health Critique of PMRA's Incident Assessment 19 Aug 2016	NA
<u>51585212</u>	18 of 18	ID 048182; Elanco Seresto 8-K	NA

5. Company Contact:

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Company Representative:

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